November 18, 2005

Mr. Michael Gallagher
Ecology PBT Coordinator
Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

RE: Comments on September 29, 2005 Version of Ecology's Proposed PBT Rule [Chapter 173-333 WAC, Persistent Bioaccumulative Toxins]

Dear Mr. Gallagher:

The American Chemistry Council (ACC) and the Chlorine Chemistry Council (CCC) appreciate this opportunity to submit comments on Ecology's revised proposed PBT Rule (Chapter 173-333 WAC Persistent Bioaccumulative Toxins). The members of both ACC and CCC are committed to the goal of reducing the potential human health and environmental risks associated with PBTs.

Overall, the revised proposed Rule represents several significant changes from the original Rule proposed by Ecology. While some improvements were made, ACC and CCC make the following recommendations to help further strengthen the proposed approach**.**

1. Consistently Use "Credible Scientific Information."

The draft Rule requires that a determination as to whether a chemical or group of chemicals meets the persistence, bioaccumulation, or toxicity criteria must be based on "credible scientific information." The requirement that scientific information be "credible" is to be commended. For consistency, however, all references to scientific information throughout the proposed Rule should be prefaced with "credible." (e.g., 173-333-410(2)(a)(iii) - information on the effects of exposure; 173-333-410(2)(a)(iv) - information on the susceptibility of sensitive populations, and; 173-333-420(1)(c) - information on "rates of diseases that have been associated with exposure to the particular PBT").

Importantly, the Rule should contain a more clear definition of "credible scientific information" to recognize the varying quality of data and studies. Application of evaluative principles would help differentiate data and studies to ensure the highest quality information is considered by Ecology. The following principles could be employed by Ecology:

a. Studies should be critically evaluated with respect to their validity and acceptability. Wherever possible, existing internationally recognized approaches for assessing the validity of studies should be applied (e.g., approaches outlined in the EU Technical Guidance Document, the Klimish scoring approach, etc.)

b. Decisions should be based on studies conducted using VALIDATED experimental guidelines (EPA, OECD, ASTM, ISO, etc), and preferably under Good Laboratory Practices.
c. Decisions should consider the "data hierarchy" of available studies and information (e.g., valid experimental/field data should take precedence over QSAR/modeled predictions, etc.).
d. Emphasis should be place on a "weight of the evidence" approach.

2. Substitutes Must Be Fully Considered and Assessed Before Being Recommended in the Creation of CAPs.

The draft Rule makes several references to "available substitutes" and "safer substitutes." It is unclear as to the evaluation process Ecology will undertake to determine the safety of a potential substitute. While use of a substitute may be one viable risk management option, any substitute should be subjected to a rigorous and defined set of criteria before a decision to use the substitute is considered. For example, the Stockholm POPs Convention sets out criteria for alternatives in Annex F (See Appendix 1), which includes a consideration of technical feasibility, costs, efficacy, risk, availability, and accessibility.

While the draft Rule requires that Chemical Action Plans include recommendations regarding the "[a]vailability, cost, and effectiveness of safer substitutes," technical feasibility, efficacy, and any risks of a proposed substitute should also be considered. Any consideration of a substitute should be on a life-cycle basis, evaluating performance and impact over the entire life-cycle of the potential substitute – including manufacture, distribution, use, maintenance and disposal. Overall, any proposed substitute must be thoroughly tested and evaluated in order to avoid inadvertently increasing risks to human health and the environment.

3. Revise Definitions of "Carcinogen" and "Development or Reproductive Toxicant."

The language used to define carcinogen should be the same as that presented in the footnote at the September 14, 2005 Advisory Committee meeting: "Carcinogen" means a chemical or chemical group that has been identified as a "known human carcinogen" or "probable human carcinogen" by the Environmental Protection Agency, as a Group 1, 2A or 2B carcinogen by the International Agency for Research on Cancer or as a "known to be human carcinogen" or "reasonably anticipated to be a human carcinogen" by the National Toxicology Program. The language that appears in the current draft, "'Carcinogen' means a chemical or chemical group that is known or suspected to increase the probability of developing cancer…" was discussed when it appeared in an earlier draft and was removed after healthy discussion by the Advisory Committee because it was unacceptably vague.

The language used to define developmental or reproductive toxicant should be the same as that presented in the footnote at the September 14, 2005 Advisory Committee meeting: "Developmental or Reproductive Toxicant" means a chemical or chemical group identified as adversely affecting development or reproduction by the National Toxicology Program, the Environmental Protection Agency, the National Institute for Occupational Safety and Health or other authoritative scientific body. The language that appears in the current draft,

"'Developmental or Reproductive Toxicant' means a chemical or chemical group that is known or suspected to cause adverse effects on development or reproduction…" was neither discussed nor agreed to by the Advisory Committee and is unacceptably vague.

4. Associate Health Effects of PBTs with Exposures.

Any discussion of health effects associated with PBTs should more explicitly require an evaluation of actual human or environmental exposure against the levels at which significant adverse effects are known to occur, noting that the established reference doses for many PBTs incorporate precautionary safety factors. In section 173-333-300 (1) the draft Rule states: "The purpose of the PBT list is to identify toxic chemicals that require further action because they remain ("persist") in the environment for long periods of time where they can bioaccumulate to levels that pose threats to human health and environment in Washington." This section should be modified to read "to levels that ~~pose threats~~ are known to cause significant adverse effects to human health and environment in Washington." Similar language should be used throughout the Rule. For example, in section 173-333-300 (2)(d), the Rule refers to the "problems associated with PBT chemicals…" without distinguishing between exposures that are not related to adverse effects and those that are known to result in harmful effects.

5. Consider Presence of a Chemical in Washington State as a Factor for Listing as PBT Chemical.

In deciding whether to list a chemical or group of chemicals as a PBT, Ecology should first conduct an analysis of the actual presence or impact in Washington State of the chemical or group of chemicals. Such an evaluation will save Ecology resources and time by focusing only on those chemicals on which Ecology can have an actual impact and the responsibility to reduce exposure to PBTs in Washington State.

6. Make Criteria for Identifying PBTs in the Rule Consistent with Other Major PBT Programs.

WAC 173-333-320 sets out the criteria by which Ecology will identify PBTs of possible interest to the State of Washington. Under these criteria, however, Ecology will likely identify a much larger group of priority chemicals than under comparable regional or international programs, creating a significant management burden on the State both in terms of assessment and diversion of limited resources with little marginal impact on health or the environment. As outlined below, ACC and CCC recommend that Ecology amend the criteria for persistence and bioaccumulation.

A. The persistence criteria for soil and sediment should be consistent with other PBT programs.

Ecology has established a half-life of 60 days in water, soil and sediment as the single criteria by which persistence is established. The North American Commission for

Environmental Cooperation's Sound Management of Chemicals (SMOC) Initiative,[1] under which the U.S., Canadian and Mexican governments have agreed to address priority PBT issues and develop Regional Action Plans (RAPs) on select chemicals, adopts persistence criteria of six months (180 days) in soil or water, and 1 year in sediment. The Stockholm Convention on Persistent Organic Pollutants (POPs)[2], a global legally-binding instrument to control emissions of the PBT-subset that are transported in air or water, adopts persistence criteria of 60 days in water, and 180 days in soil or sediment.

ACC and CCC recommend that Ecology adopt persistence criteria for soil and sediment that are consistent with the North American regional program and internationally agreed programs. In the case of the Stockholm Convention, for example, the criteria were adopted after lengthy negotiations on the criteria that would assure the identification of potential chemicals of concern, and have a well-accepted scientific basis.

B. Ecology should adopt a bioaccumulation or bioconcentration factor of 5,000.

The rule establishes that a bioaccumulation (BAF) or bioconcentration factor (BCF) of 1,000 identifies a chemical as bioaccumulative. In the absence of such data, an octanol-water partition coefficient ($LogK_{0w}$) of 5 establishes the bioaccumulative characteristic under the rule. ACC and CCC believe the BAF and BCF criteria should more properly be 5,000.

Ecology should be aware that a $LogK_{0w}$ of 5 is very closely associated with BAFs and BCFs of 5,000, not 1,000. In the context of the negotiations on the Stockholm Convention, the International Council of Chemical Associations (ICCA), of which ACC is a member, reviewed the technical basis for concluding that $LogK_{0w}$ 5 is equivalent to a BCF of 5,000. A copy of that paper, developed for the Criteria Expert Group (CEG) that met during the Stockholm Convention negotiations, is contained in Appendix 2.

Further, in both the North American SMOC initiative and the Stockholm Convention BCF and BAF values of 5,000 are used to identify chemicals as bioaccumulative. Again, there is a strong scientific basis for setting bioaccumulation values at 5,000. Setting BCF and BAF factors at the low level of 1,000 risks identifying substantially more chemicals as potential candidates for Washington's PBT program – particularly chemicals that do not pose a risk to human health or the environment.

C. *Ecology should modify the language for degradation products.*

In the proposed Rule, section 173-333-320(3) on degradation products reads:

> "Ecology will consider both the chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a chemical does not meet the criteria in this section for a PBT but degrades into chemicals that do meet the criteria in this section for a PBT, the

[1] The North American Commission for Environmental Cooperation's *Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemical Initiative* (Oct. 1997).
[2] *Stockholm Convention on Persistent Organic Pollutants, Annex D (opened for signature May 23, 2002).*

parent chemical will be considered in the development of a CAP for those derivative chemicals."

The Advisory Committee agreed that if a chemical was not a PBT, but degraded into a PBT, the degredate would be listed, but the parent would not be listed (but could be considered for regulation in the CAP). To better reflect the recommendation of the Advisory Committee, this section should be clarified to read as follows:

> "Ecology will consider both the chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a chemical does not meet the criteria in this section for a PBT but degrades into chemicals that do meet the criteria in this section for a PBT, the parent chemical will not be listed as a PBT but will be considered in the development of ~~a~~ CAP**s** for those ~~derivative chemicals~~ degradation products that do meet the criteria in this section for a PBT and are on the PBT list**."**

7. Ecology Should Ensure Integration of National and Regional Action Plans into CAPs.

In developing the Chemical Action Plans (CAPs), Ecology should ensure integration of existing Action Plans. Under the U.S. EPA PBT Chemical Program, the Agency is developing PBT Action Plans for priority PBT chemicals. In addition, North American Regional Action Plans (NARAPs) have been developed under the North American Commission for Environmental Cooperation (NACEC). These NARAPs were developed with input from Canada, U.S., Mexico, and interested stakeholders and reflect a regional perspective on existing international agreements, policies, and laws. Several EPA PBT Action Plans and NARAPs are in the implementation or development phase. Ecology should take advantage of these significant efforts and integrate any overlapping CAPs with these existing Action Plans.

8. Identification of Funding Sources Should Not Be Included in the CAP.

Section 173-333-420 (1)(g)(ii) of the draft Rule, identifying potential funding sources ("PBT sources and products") for implementing CAPs, should be modified. Specifically, the reference to "including those that tie implementation costs to PBT sources and products" should be removed or modified. A more holistic approach would be "including an analysis of the impact and appropriateness of potential funding mechanisms." While certain economic instruments and market-based mechanisms may be appropriate, the state must carefully evaluate the impact and appropriateness of such mechanisms. In evaluating potential economic instruments it is important to emphasize the following:

a. Potential costs on a subset of products or processes may result in violation of the interstate commerce clause.
b. Potential costs on particular products or processes within a state are unlikely to be the most effective mechanism and can have unintended market distorting impacts. Any such policies need to first consider how this would impact in-state versus out-of state or out of country sources and products.

c. Potential costs on products or processes, assumes that the product or process is the resulting source impacting human health or the environment, when in fact such impacts may be the result of misuse by consumers or a consuming industry.

d. Potential costs on products or processes disregard the benefits of products and processes, which can provide critical benefits that are essential to society.

9. Include Ambient Monitoring as Consideration When Updating PBT List.

Section 173-333-340 (2) calls for Ecology to periodically review and update the list of PBT chemicals. In addition to the considerations listed in this section, Ecology should also consider the results of ongoing 'ambient monitoring' when reviewing and updating the PBT list. The results of ambient monitoring will help inform Ecology as to the levels a chemical is present in Washington State and help determine the relative risk represented by that PBT. This consideration should also include an evaluation of environmental monitoring trend data to determine whether levels in the environment are increasing, decreasing, or relatively constant. Monitoring trends can also help inform Ecology as to the appropriate level of priority for action on a chemical.

10. Replace the Term "Body-Burden" with "Biomonitoring."

Section 173-333-420(1)(d) states "This will include consideration of available information on the levels of the PBT present in Washington's environment, the likely fate and transport mechanisms, available **body-burden data**, toxicity effects, and the rates of diseases that have been associated with exposure to the particular PBT." Rather than refer to "body-burden" data, the Rule should refer to "biomonitoring" data. Biomonitoring is the more commonly used and accepted term for data on levels of chemicals in the body. Also, "biomonitoring" is the term used by the U.S. Centers for Disease Control and Prevention.

11. The Advisory Committee Process Should Incorporate More Scientific Expertise.

An advisory committee provides valuable external stakeholder input to the PBT management process. While we generally agree with the suggested representatives for the committee, including more science-based expertise and less advocacy input may be more valuable to Ecology. Specifically, the inclusion of qualified scientific experts in areas such as medical toxicology, risk assessment, epidemiology, and/or analytical chemistry could provide important science-based input to the process.

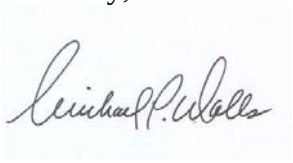
12. Conclusion

Overall, with a few key changes, the revised PBT Rule represents a workable approach to the risk-based management of PBT chemicals that represent risks to human health and the environment. We continue to recommend that Ecology apply the process presented in the Rule in its proposed form for a term of three to five years to allow time to learn the Rule's strengths and limitations. Upon future evaluation, Ecology could make necessary changes and begin adapting the criteria to add or drop specific substances. Given the careful thought and discussion

Ecology and the Advisory Committee devoted to the development of the proposed Rule, Ecology should now give the process a chance to work.

Thank you for this opportunity to comment on this Rule. If you have any questions about these comments, please direct them to Greg Merrill, at (703) 741-5417, or to Mike Walls, at (703) 741- 5167.

Sincerely,



Michael P. Walls
Managing Director
Health, Products and Science Policy
American Chemistry Council

Clifford T. "Kip" Howlett, Jr.
Executive Director,
Chlorine Chemistry Council
Vice President
American Chemistry Council

cc: Association of Washington Business

APPENDIX 1

Stockholm POPs Convention
Annex F

INFORMATION ON SOCIO-ECONOMIC CONSIDERATIONS

An evaluation should be undertaken regarding possible control measures for chemicals under consideration for inclusion in this Convention, encompassing the full range of options, including management and elimination. For this purpose, relevant information should be provided relating to socioeconomic considerations associated with possible control measures to enable a decision to be taken by the Conference of the Parties. Such information should reflect due regard for the differing capabilities and conditions among the Parties and should include consideration of the following indicative list of items:

(a) Efficacy and efficiency of possible control measures in meeting risk reduction goals:

(i) Technical feasibility; and
(ii) Costs, including environmental and health costs;

(b) Alternatives (products and processes):

(i) Technical feasibility;
(ii) Costs, including environmental and health costs;
(iii) Efficacy;
(iv) Risk;
(v) Availability; and
(vi) Accessibility;

(c) Positive and/or negative impacts on society of implementing possible control measures:

(i) Health, including public, environmental and occupational health;
(ii) Agriculture, including aquaculture and forestry;
(iii) Biota (biodiversity);
(iv) Economic aspects;
(v) Movement towards sustainable development; and
(vi) Social costs;

(d) Waste and disposal implications (in particular, obsolete stocks of pesticides and clean-up of contaminated sites):

(i) Technical feasibility; and
(ii) Cost;

(e) Access to information and public education;

(f) Status of control and monitoring capacity; and

(g) Any national or regional control actions taken, including information on alternatives, and other relevant risk management information.

APPENDIX 2

INTERNATIONAL COUNCIL OF CHEMICAL ASSOCIATIONS

ICCA BRIEFING PAPER
LOG K_{OW} CRITERIA OF 5 IS EQUIVALENT TO BCF CRITERIA OF 5,000

In Annex I of the "Report of the First Session of the Criteria Expert Group for Persistent Organic Pollutants" (UNEP/POPS/INC/CEG/1/3; October 30, 1998) the first criterion states that a substance would meet the bioaccumulation criterion if there is "evidence that the BCF or BAF in aquatic species for the substance is greater than 5,000 or in absence of BCF/BAF data, the log K_{ow} is greater than [4][5]". This criterion appropriately establishes the primacy of measured BCF[1] and/or BAF[2] data over the log K_{ow}[3] surrogate. However, there is an outstanding issue of whether the log K_{ow} value of 4 or 5 is the most appropriate equivalent to the primary BCF criteria of 5,000. This document will address this equivalence using the available and generally accepted relationship between BCF and log K_{ow}.

Relationships between Log Kow and BCF

There are several accepted relationships for calculating BCF from log K_{ow} values for non-polar, hydrophobic organic chemicals that have been and continue to be used in regulatory applications and which are based on large databases (Table 1). Furthermore, these relationships would yield similar BCF values for log K_{ow} values up to a log K_{ow} of 6. For substances with log K_{ow} values greater than 6, the BCF values appear to *decrease* with increasing log K_{ow}. Curvilinear relationships (e.g., Bintein et al., 1993) have been proposed to predict BCF for log K_{ow} values greater than 6. However, because of experimental difficulties in measuring BCF values for substances in this high log K_{ow} range, these QSARs (quantitative structure-activity relationships) and the predicted BCF values should be used with caution. Because of the decrease in BCF with increasing log K_{ow}, an upper cut-off criterion for log K_{ow} is proposed. Based on experience with bioaccumulative substances and curvilinear QSARs (e.g. Bintein et al., 1993), the upper bound appears to be approximately at a log K_{ow} value of 7.5.

Table 1. Commonly Used QSARs for Estimating BCF.

Relationship	R^2	Reference
log BCF = (0.85*log K_{ow}) - 0.7	0.95	Veith et al. 1979 and EC 1996
BCF = 0.048*K_{ow}	0.97	Mackay (1982)
log BCF = (0.79*log K_{ow}) - 0.4	0.93	Veith and Kosian (1983)
log BCF = (0.910*log K_{ow}) - (1.975*log (6.8E-7*K_{ow} +1)) -0.786	0.95	Bintein et al. 1993

Log K_{ow} value that Corresponds to BCF criteria of 5,000

The BCF is used to derive the appropriate K_{ow} criteria because it represents the direct accumulation of the substance, i.e. the property of the substance that is of primary concern. Based on the QSARs used in the US, EU and Canada, the value of log K_{ow} corresponding to the BCF criterion of 5000 is in the range of 5 to 7.5 (Table 2).

Table 2. Log K_{ow} values Equivalent to a BCF of 5000 for Commonly Used QSARs for Estimating BCF.

Relationship	log Kow for BCF = 5000	Reference
log BCF = (0.85*log K_{ow}) - 0.7	5.2	Veith et al. 1979 and EC 1996
BCF = 0.048*K_{ow}	5.0	Mackay (1982)
log BCF = (0.79*log K_{ow}) - 0.4	5.2	Veith and Kosian (1983)
log BCF = (0.910*log K_{ow}) - (1.975*log (6.8E-7 K_{ow} +1)) -0.786	5.0 and 7.5	Bintein et al. 1993

It has also been determined that substances with a molecular weight (MW) > 1100 are too large to cross membranes into the organism (EEC 1993). Thus, the full recommendation for a secondary criterion equivalent to the proposed primary criterion would be:
5.0 < log K_{ow} < 7.5 **and** MW < 1100

Limitations of Log K_{ow} as a Secondary Criterion

Although it is possible to use these QSARs to estimate BCF for non-polar organic substances, it is important to recognize that none of these QSAR relationships account for metabolism explicitly, although the QSARs may have included BCF data for some substances that could have been metabolized. In fact, the wide variability in measured BCF values is in part due to metabolism. Metabolism can result in measured BCF values for these chemicals that are significantly less than those that would be determined from the log K_{ow}. For example, the BCF for pentachlorophenol is calculated to be 5,500 but the measured value is 195 (Kukkonen and Oikari 1988) and that for dodecylbenzene is calculated to be 10,232,930 versus a measured value of 25 (Werner and Kimerle 1982).

Other examples are given in Table 1 of ECETOC (1996) and the dissertations of Sijm (1992) and De Wolf (1992). Thus, the log K_{ow} of 5 would be considered conservative, in some case extremely conservative, since if there is any metabolism the estimated BCF would be higher than the measured BCF.

References

Bintein, S., J. Devillers and W. Karcher. 1993. Nonlinear dependence of fish bioconcentration on n-Octanol/water partition coefficients. SAR and QSAR in Env. Res. 1:29-39.

de Wolf, W. 1992. Influence of biotransformation on the bioconcentration of chemicals in fish. Ph.D. Dissertation. University of Utrecht, The Netherlands.
EC. 1996. Technical Guidance Manual

EEC. 1993. Technical guidance documents in support of the risk assessment directive (93/67/EEC) for substances notified in accordance with the requirements of Council Directive 67/548/EEC. Brussels, Belgium.

ECETOC 1996. The role of bioaccumulation in environmental risk assessment: The aquatic environment and related food webs. Brussels, Belgium.

Kukkonen, J. and A. Oikari. 1988. Sulphate conjugation is the main route of pentachlorophenol metabolism in Daphnia magna. Comp. Biochem. Physiol. 91C:465-468.

Mackay, D. 1982. Correlation of bioconcentration factors. Env. Sci. Technol. 16: 274-278

Sijm, D. 1992. Influence of biotransformation and toxicity of chlorinated aromatic compounds in fish. Ph.D. Dissertation. University of Utrecht, The Netherlands.

Veith, G.D., D.L. Defoe and B.V. Bergstedt. 1979. Measuring and estimating the bioconcentration factor of chemicals on fish. J. Fish. Res. Board Can. 36:1040-1048.

Veith, G.D. and P. Kosian. 1983. Estimating bioconcentration potential from octanol/water partition coefficients. In: Mackay, D., Paterson, S., Eisenreich, S.J., Simons, M.S. (eds). Physical behavior of PCBs in the Great Lakes, Ann Arbor Sciences Publishers, Ann Arbor, P. 269-282.

Werner, A.F. and R.A. Kimmerle. 1982. Uptake and distribution of C12 alkylbenzene in bluegill (*Lepomis macrochirus*). Environ. Toxicol. Chem. 1:143-146.

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[1] bioconcentration factor
[2] bioaccumulation factor
[3] logarithm to base 10 of the octanol / water partition coefficient